

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse, Rm 900 2nd & Chestnut St Philadelphia, PA 19106 (215) 597-4390 Fax: (215) 597-0875 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 05/06/2011
	FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Malcolm J. Sonnen, Owner/SE Prevention Plan Administrator

FIRM NAME Malcolm Sonnen Farm	STREET ADDRESS 101 Sonnens Road
CITY, STATE, ZIP CODE, COUNTRY Richland, PA 17087	TYPE ESTABLISHMENT INSPECTED Shell Egg Producer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Your firm does not have a written SE prevention plan that is specific to the farm where you produce eggs.

Specifically, from 7/9/10 to 11/18/10 your firm did not implement a SE Prevention Plan while producing shell eggs for the table market. The current SE Prevention Plan on file is dated 11/19/10.

OBSERVATION 2

When your monitoring indicated unacceptable fly activity within a poultry house, appropriate methods were not used to achieve satisfactory fly control.

Specifically, your SE Prevention Plan states on page 9 that you will replace used fly (b) (4) with "(b) (4)" in (b) (4) day intervals. A review of your fly monitoring records revealed that you failed to replace (b) (4) in (b) (4) day intervals. Your SE Prevention Plan also states on page 9, that "an average number count of (b) (4) per (b) (4) is typically considered a recommended threshold for initiating house fly control measures". Your fly monitoring records were observed to exceed the stated threshold of (b) (4) as follows:

- 10/05/10 through 10/16/10 - 11 days; 395 average fly (b) (4) count
- 11/17/10 through 11/29/10 - 12 days; 670 average fly (b) (4) count
- 11/29/10 through 12/07/10 - 8 days; 402 average fly (b) (4) count
- 12/07/10 through 12/22/10 - 15 days; 502 average fly (b) (4) count
- 01/31/11 through 02/07/11 - 8 days; 540 average fly (b) (4) count
- 02/07/11 through 02/15/11 - 8 days; 397 average fly (b) (4) count
- 02/15/11 through 02/21/11 - 7 days; 257 average fly (b) (4) count
- 02/21/11 through 02/27/11 - 6 days; 245 average fly (b) (4) count

OBSERVATION 3

Stray animals are not prevented from entering poultry houses.

Specifically, there were several location along the roof eaves (North Side of Poultry House) which lacked a barrier or had

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Michael J. Mero, Investigator Brandon J. Brookens, Investigator	DATE ISSUED 05/06/2011
	<i>Michael J. Mero</i> <i>Brandon J. Brookens</i>	

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damaged wire to prevent wild bird entry into the poultry house. This included a large hole in the wire barrier located under the roof eave at the north east corner of your poultry house. Additionally, two wild birds were observed exiting the poultry house on the north side of the building where the wire barrier was damaged.

OBSERVATION 4

Your written SE prevention plan is not fully implemented and followed.

Specifically,

- you failed to implement fly monitoring using (b) (4) from 07/09/2010 to 10/04/2010.
- you failed to monitor and record refrigeration temperatures from 07/09/2010 to 10/04/2010.

OBSERVATION 5

Supervisory personnel responsible for ensuring compliance with the SE prevention plan(s).

did not review refrigeration, rodent, and fly monitoring records from 07/09/10 to 05/06/11

OBSERVATION 6

All your required records do not include the time of the activity that the records reflect.

Specifically, rodent monitoring records do not include the time of the activity from 07/09/10 through 03/02/11 as required.

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	<i>[Handwritten signatures]</i>	